IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., et al., Plaintiffs, v. LUPIN LTD., et al., Defendants.	C.A. No. 09-037 (RBK) (JS) (CONSOLIDATED)
SHIONOGI INC., et al., Plaintiffs, v. MYLAN INC., et al., Defendants.	C.A. NO. 10-135 (RBK) (JS)

THE LUPIN DEFENDANTS' OPENING BRIEF IN SUPPORT OF MOTION TO STAY OR MODIFY ENFORCEMENT OF THE COURT'S PRELIMINARY INJUNCTION ORDER

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I. NATURE AND STAGE OF THE PROCEEDINGS

Lupin Ltd. and Lupin Pharmaceuticals USA (collectively "Lupin") submit this opening brief in support of their motion to stay or modify enforcement of the preliminary injunction entered December 6, 2011 (the "Order"), pending resolution of their appeal to the Federal Circuit Court of Appeals under Federal Rule of Civil Procedure 62(c). Lupin requests this Court to modify the terms of the order to provide that the injunction will be lifted if Watson Laboratories, Inc. or another company enters the generic Fortamet® market, which would restore the balance among the parties. In other words, Lupin asks that the Court restore the *status quo*. Lupin is filing a motion requesting an expedited briefing and argument schedule in the Federal Circuit.

II. SUMMARY OF ARGUMENT

Lupin is likely to succeed on the appeal. First, this Court applied an incorrect standard of proof in evaluating the validity of the patent and disregarding evidence of obviousness. Second, the Court applied an erroneous standard of proof on infringement and thus unduly discounted the only test results of Lupin's product, instead ruling in effect that Lupin was bound by the mandated description of the brand product on its label even though the test reflected on the label is not the same test required by the patent claims. Third, Lupin will suffer irreparable harm from a wrongfully-granted preliminary injunction that alters the *status quo*, which is the relevant question for the Court on a motion for a stay.

III. STATEMENT OF FACTS

The Court is familiar with the facts, so they will be summarized only briefly here. Lupin incorporates by reference its Answering Brief in Opposition to Plaintiffs' Motion for Preliminary Injunction and Recall ("Lupin Mem.") and the supporting declarations, as well as the exhibits and related slides submitted at the oral argument.

A. Procedure in the Patent & Trademark Office (PTO)

One unusual feature of this case is that the patent under which this Court enjoined Lupin from marketing its product is not the patent that the patent examiner ultimately allowed, but rather is a patent that contains claims that both the examiner and the prosecuting attorney agreed should not have issued. This Court found that the patentees requested that claim 1, among other claims, be cancelled and that the examiner, after initially allowing claim 1, issued a Supplemental Notice of Allowability which deleted claim 1. (Slip Op. at 12.) The Court found this "puzzling" and noted that "it is unclear how claim 1 came to be included in the final version of the patent." (Slip Op. at 12.) Nevertheless, the Court enjoined Lupin in enforcement of claim 1.

The chronology is undisputed. On November 20, 2003, there was an in-person examiner interview. The next day, the patentee submitted an amendment canceling claim 1, the broadest claim which included a T_{max} range of "5.5 to 7.5 hours," and amending the claims to limit the top of the T_{max} range to "7 hours." The examiner then issued a Notice of Allowance which allowed the cancelled claims and did not refer to the notice of cancellation. Over the next few months, the patentee attempted on three occasions to correct the claims allowed. In November 2004, the PTO issued a Supplemental Notice of Allowance for the correct claims. Another mistake by the PTO resulted in printing the claims from the first, superseded allowance, instead of the claims that both the patent applicant and the examiner intended to include in the issued patent.

B. Lupin's ANDA Product

In accordance with FDA requirements, Lupin's package insert copied that of the brand product, including the results of a test of Fortamet® under conditions different from those stated in the patent. The test reported in the package insert was of C_{max}, T_{max} and AUC after multiple

doses taken over several weeks until a steady state was reached. In contrast, the test required by the patent is of a single dose after dinner, explicitly without reaching a steady state.[1]

There were two tests of Lupin's ANDA product discussed at the preliminary injunction hearing. One measures T_{max} after a single dose administered after dinner, as stated in claim 1 of the patent. The other measures T_{max} after a single dose administered after breakfast, and was submitted to the FDA to show that Lupin's product is bioequivalent to the brand product. Both tests show a T_{max} well over the top of the patented range, using either the ultimately allowed or the mistakenly-printed claim 1. (*See* Lupin Mem. at 10-13; Lupin Merits Slides #5, 12-13; Expert Declaration of Alexander Shepherd ("Shepherd Decl.").) Plaintiffs did not offer contrary test data on Lupin's product.

C. The Market for Fortamet

Lupin's launch of its generic version of Fortamet triggered Watson's right to market an authorized generic version and Shionogi has no ability to control whether or when it will go on the market. (*See* Lupin Mem. at 31-32.) The indications in the record are that Watson is preparing to launch its authorized generic. (*See* Lupin Slides re Irreparable Injury and Recall ("Lupin Injury Slides") #11 and Exhibit Binder Tabs 16 & 17; Declaration of Robert G. Hoffman ("Hoffman Decl.") at ¶5.)

[1] The Court's decision states that "Lupin does not dispute that its label expresses" "a mean T_{max} of 6 hours when administered after dinner." (Slip Op. at 9.) This is not accurate; Lupin explained at argument and in its opposing papers that the test of the package label was not the test of the patent. (*See* Lupin Mem. at 17-18 (" Not only does Lupin's package insert report on tests conducted on a different product (Fortamet®), but the tests themselves are not those required by the patent for determining infringement. The patent claim requires tests of a single dose, but the package insert table involves administration of multiple doses. The package insert refers to a reported T_{max} for the "steady state," which by definition involves multiple doses, and also describes that the patients received doses once or twice a day for four weeks."); Lupin Slides re Likelihood of Success on the Merits ("Lupin Merits Slides") #19-23.) The transcript of the argument is not yet available.

IV. ARGUMENT

A. Legal Standard

In deciding whether to grant a motion under Rule 62(c), a court should consider "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether the issuance of a stay will substantially injure the other parties interested in the proceedings; and (4) where the public interest lies." *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (citing *Hilton v. Branskill*, 481 U.S. 770, 776 (1987)); *see Combustion Sys. Servs., Inc. v. Schuylkill Energy Res., Inc.*, 153 F.R.D. 73, 74 (E.D. Pa. 1994). "Each factor . . . need not be given equal weight." *Standard Havens Prods., Inc.,* 897 F.2d at 512. "[W]here the possibility of irreparable harm favors issuance of the stay and harm to third parties seems minimal, the showing which the moving party must make will not be as rigorous." *Kawecki Berylco Indus., Inc. v. Fansteel*, 517 F. Supp. 539, 541 (E.D. Pa. 1981). The likelihood of success on the merits is not a rigid concept within Rule 62(c). *Standard Havens*, 897 F.2d at 512; *Tristrata Techn., Inc. v. ICN Pharmaceuticals, Inc.*, 2004 U.S. Dist. Lexis 6557, *6-7 (D. Del. Apr. 12, 2004).

The Court's earlier imposition of an injunction does not preclude the grant of a stay pending appeal. Granting a stay does not imply that the Court believes it rendered an erroneous decision, but merely that it has ruled on a difficult legal question and the equities of the case suggest the *status quo* should be maintained. *Standard Havens*, 897 F.2d at 515, 516; *E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987); *Washington Metro. Area Transit Com. v. Holiday Tours, Inc.*, 559 F.2d 841, 844-45 (D.C. Cir. 1977). In *Combustion Systems*, 153 F.R.D. at 74, the court granted the motion because "although the Court will not concede that it committed error, this [C]ourt cannot conclude that

[the movant] has no reasonable possibility of success on the merits of its post trial motions or appeals" and the non-moving party would not be substantially harmed by the a stay. A stay is appropriate where there is a "reasonable possibility – albeit not a probability – that [the court] was in error." *First Amendment Coalition v. Judicial Inquiry & Review Bd.*, 584 F. Supp. 635, 636-38 (E.D. Pa. 1984) (quoting *Evans v. Buchanan*, 424 F. Supp. 875 (D. Del. 1976), *aff'd as modified*, 555 F.2d 373 (3d Cir. 1977)).

"The purpose of staying an injunction pending appeal is to preserve the status quo." *Kawecki Berylco Indus., Inc. v. Fansteel*, 517 F. Supp. 539, 542 (E.D. Pa. 1981). The *status quo* before the injunction issued in this case was that either both Lupin and Watson or neither of them could make new sales of their generic metformin products. That status has been changed.

B. Lupin Is Likely To Succeed In Vacating The Injunction Because The Court Applied The Wrong Burden Of Proof Concerning Invalidity

The Court erroneously held that "a challenger must prove invalidity by clear and convincing evidence – a high threshold that Lupin cannot meet at this stage." (Slip Op. at 11.) That it would be extremely difficult to meet a clear and convincing burden of proof in the context of a preliminary injunction proceeding helps explain why this is not the correct standard of proof at this stage of the litigation. The Court relied on *Microsoft Corp. v. i4i Ltd.P'ship*, 131 S.Ct. 2238, 2242 (2011), but that decision involved the standard of proof at trial, not a preliminary injunction hearing. For a preliminary injunction, the burden on the alleged infringer is only to raise a substantial question regarding either infringement or validity. *See Altana Pharma AG v. Teva Pharma USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009). "The accused infringer does not face the clear and convincing evidence burden of proof applicable at trial." *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, 2011 WL 2161072, at * 2 (Fed. Cir. June 1, 2011) (non-precedential), *reh'g and reh'g en banc denied,* 2011 WL 4495619

(2011); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). The lower standard is because a preliminary injunction is an extraordinary remedy, not to be imposed lightly. *See Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms. Inc.,* No. 2011-1611, slip. op. at 7 (Fed. Cir. December 12, 2011) (non-precedential) (citing *Winter v. Natural Res. Def. Council, Inc.,* 555 U.S. 7, 20 (2008) (attached as Attachment A); *King Pharms. Inc. v. Sandoz, Inc.*, C.A. No. 08-5974, 2010 WL 1957640, at *1 (D.N.J. May 17, 2010 (Brown, Ch. J.) (not for publication); *EMSL Analytical, Inc. v. Testamerica Analytical Testing Corp.,* Civ. No. 05-5259, 2006 WL 892718, at *2 (D.N.J. April 4, 2006).

Applying the proper standard, Lupin clearly has raised a substantial question as to the validity of the '866 patent. The declaration of Lupin's expert Dr. Kenneth Morris explains why, especially after the Supreme Court's decision in *KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398 (2007), these claims are invalid as obvious under 35 U.S.C. §103(a). (*See also* Lupin Mem. at 18-21.) Moreover, the claims that issued in the '866 patent were the wrong claims, as discussed above and as detailed in the expert declaration of Arthur Steiner ("Steiner Decl."), a former patent examiner with 40 years of experience with patent law. (Steiner Decl., especially ¶¶ 12 *et seq*.) Shionogi did not introduce any evidence to rebut Mr. Steiner's analysis, and Shionogi's disagreement with Dr. Morris failed to carry Shionogi's burden to show a lack of substantial merit in the obviousness defense.

Nor did the patent examiner side with Shionogi. The prosecution history of the '866 patent shows that, through PTO error, claim 1 with a T_{max} range ceiling of "7.5 hours" was included in the patent, when in fact the examiner had rejected claim 1 as obvious with that maximum. The examiner ultimately only approved claims with a T_{max} ceiling of "7 hours" in the face of prior art disclosing, for example, a T_{max} of 8 hours.

This Court, however, focused on the initial allowance of the claims. The claims that were allowed and intended to be issued are not the claims that appear in the published patent. Whether claim 1 was cancelled and withdrawn because the examiner's concerns could not be met in time to make a deadline, as plaintiff asserts (*see* Plaintiff Shionogi Inc.'s Reply In Support of Motion for Preliminary Injunction and Recall at 11, fn. 11), or because the examiner had concluded it was obvious and the applicant wanted a defensible patent, as Lupin argues, is irrelevant. In either case, this Court has enjoined Lupin based on enforcement of a patent that was issued by a printer's mistake.

Even though Shionogi could have asked the PTO to correct the error, Shionogi has been content to enforce the erroneously printed patent claims. Contrary to the representation made by Shionogi's counsel during the preliminary injunction hearing, this Court lacks authority to correct the error. See *Group One, Ltd. v. Hallmark Cards, Inc*., 407 F.3d 1247, 1302-03 (Fed. Cir. 2005) (district court does not have authority to correct error in patent that cannot be seen "simply by reading the patent"). The error here is not evident on the face of the patent. The prosecution history discloses that the missing language was required to be added by the examiner as a condition for issuance, but one cannot discern what language is missing simply by reading the patent. The district court does not have authority to correct the patent in such circumstances."); (*see also* Lupin Mem. at 22-23, fn. 22.)

The Court also erred by neglecting to address the substance of defendants' argument that the patent is invalid for obviousness. *See Warner Chilcott Labs.,* slip op. at 10-11 (vacating a preliminary injunction barring generic marketing in a Hatch-Waxman case because the district court "failed to make any findings as to Mylan's invalidity challenge"). It appears that the Court overlooked defendants' challenge to the validity of the patent for obviousness. Rather than

analyze the merits of the argument, the Court relied on another misinterpretation of the burden of proof, citing *ACS Hospital Systems, Inc. v. Montefiore Hospital,* 732 F.2d 1572, 1574-75 (Fed. Cir. 1984). But *ACS Hospital Systems* did not hold that the presumption of validity is overpowering at the preliminary injunction (or any) stage; it merely held that the presumption of validity is a "procedural device" for keeping the burden of proving invalidity with the alleged infringer, regardless of the strength of evidence of invalidity. The presumption of validity means that the burden of proof never shifts, but it does not mean that invalidity can never be established. There is a likelihood that the appellate court will find reversible error in the Court's failure to use the correct standard of proof and to address the merits of Lupin's argument that the patent is obvious.

C. Lupin Is Likely To Succeed In Vacating The Injunction Because The Court Erroneously Held That The Label Was A Binding Admission and Dismissed The Only Pertinent Test Data of Lupin's Product.

There is no basis for the Court to disregard of the test results of Lupin's product because of the statement on the label. First, the results reflected on the label are of a different test from that in the patent. The patent requires measuring T_{max} after a single dose administered following dinner where "the drug plasma concentration has not achieved steady state." ('866 Patent, Col. 7, lines 60-62.) The test on Lupin's label measured T_{max} after multiple doses over four weeks achieved a steady state drug plasma concentration. (Lupin Mem. at 18.) Thus, the test results reported on the label do not address the infringement question because it is the wrong test.

Second, the label reports the results of tests of Fortamet®, not of Lupin's product. As stated at the preliminary injunction hearing, Lupin understood that it was required to copy the data from the Fortamet® label, and indeed subsequent to the hearing Lupin confirmed with the FDA that Lupin could not delete the data or clarify that the data was for Formatet®. (Declaration of Leslie Sands dated December 13, 2011, at ¶¶ 3-7.) The FDA found Lupin's

product bioequivalent to Fortamet®, despite test results submitted to the FDA showing that Lupin and Fortamet® gave different values for C_{max} and AUC,[2] and the FDA approved Lupin's package insert.[3] Thus, the relevance of the label for this motion is limited to the evidentiary question of whether the statement with respect to T_{max} should be considered a binding admission on Lupin, since it is not factual proof of the T_{max} of Lupin's product. Inasmuch as all of the factual proof is that Lupin's product does not produce an infringing T_{max}, the Court's conclusion that Lupin's noninfringement defense lacks substantial merit is clearly erroneous.

The citation to *In re Brimonidine Patent Litig.*, 643 F.3d 1366, 138 (Fed. Cir. 2011), Opinion at 11, to support the Court's conclusion and for its reliance on *Abbott Labs v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002), is misplaced, because that decision does not hold that test results should not be considered. To the contrary, the *Brimonidine* court stated that in *Abbott,* "[w]e vacated the district court's award of summary judgment of noninfringement in favor of TorPharm because there was a disputed issue of fact concerning the number of subunits in the formulation that TorPharm would produce if it operated in compliance with its ANDA. In that instance, we held that it might be appropriate for the court to consider material outside the four corners of the ANDA to determine whether the ANDA describes an infringing product." *In re Brimonidine Patent Litig.*, 643 F.3d at 1378.

Finally, the Court's apparent conclusion that so long as infringement experts disagree, Lupin has no substantial defense of noninfringement, is error. Not only does this misplace the burden of proof (which is on Shionogi) but it also ignores that the Court is not faced with

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[2] These are the relevant parameters for a determination of bioequivalence. T_{max} is not considered for bioequivalence, although the after-breakfast study submitted by Lupin also showed higher T_{max} than the patented range. (Lupin Mem. at 12.)

[3] The FDA approves the package insert or label as well as the ANDA product. 21 U.S.C. 355(j)(2)(A)(v).

competing test results. The only direct evidence of the T_{max} of Lupin's product shows that it falls outside the patented range, and the fact that plaintiff's expert criticizes that test while defendant's expert supports it does not mean that the Court must reject it at this stage of the proceeding. The Court was in error here not because it refused to resolve a battle of the experts at an early stage, as it stated it was doing, (Slip Op. at 9); but because the Court resolved that battle before it was fought, in favor of plaintiff's expert, by refusing to consider the test results that proved the absence of infringement. *See Warner Chilcott Labs.,* slip op. at 8-10 (vacating a preliminary injunction barring generic marketing in a Hatch-Waxman case because the district court had not held a hearing to resolve a "battle of experts"); (*see also* Lupin Mem. at 11-13, Shepherd Decl. at ¶¶ 8-25, and Lupin Merits Slides #13-14 for an explanation of why plaintiff's expert's criticisms, even if accepted, do not undercut the conclusion of the test).

The Court reversed the proper burden of proof on infringement, finding that Lupin had failed to show its noninfringement defense had substantial merit, although it was Shionogi's burden to provide some actual evidence that Lupin's defense lacked substantial merit. "[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1350-51 (Fed. Cir. 2001). Again, the only pertinent test involving administration of a single dose of Lupin's product points to a T_{max} of 12 hours.

Moreover, the significance of the statement on the label is a question of law and this Court's decision is one of first impression since *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The two cases cited by Shionogi both were decided before *Pliva* and, in any event, both considered evidence in addition to the label. In *Abbott Labs*, 300 F.3d 1367, the additional evidence was consistent with the label and indeed the accused infringer offered no relevant

evidence to rebut infringement; the court relied on this consistent test data as well as the label to find that the product infringed. In *Research Foundation of State Univ. of N.Y. v. Mylan Pharms., Inc.*, 723 F. Supp. 2d 638 (D. Del. 2010), the generic company represented that the relevant parts of the label were accurate with respect to the generic product; nevertheless, the Court also considered the scientific evidence outside the label. After trial finding no infringement, the District Court concluded that its reliance on the label at the preliminary injunction stage rather than on the evidence directly concerning the challenged product "does not withstand scrutiny." 2011 WL 3796228 at *23 (D. Del. Aug. 26, 2011).

Contrary to a case like *Abbott*, Lupin's ANDA does not report that Lupin's product gives a T_{max} of 6 hours (or any other number between 5.5 and 7.5 hours) when administered in a single dose following dinner. Not only does the label thus not address infringement (because it reports the result of a different test on a different product), but also the Court should not have relied on the label instead of on the actual results of the pertinent tests in light of the Supreme Court's decision in *Pliva.*

Pliva confirmed that the generic company is not responsible for the accuracy of the label and has little choice under FDA regulations but to copy the brand's label virtually verbatim. Therefore, especially in the presence of test evidence showing non-infringement, a statement on the label suggesting (or even stating) the contrary cannot by itself be sufficient proof of infringement to support a preliminary injunction, because per *Pliva* there is no representation by Lupin that the copied data accurately describes the generic product. Since this Court's reliance on the label goes well beyond the existing case law and raises significant questions of the role of the package insert in Hatch-Waxman patent infringement cases, the Court should stay the preliminary injunction pending Federal Circuit review.

V. LUPIN WILL BE IRREPARABLY HARMED IF THE INJUNCTION IS NOT STAYED PENDING APPEAL

On this motion, the question is whether failing to stay or modify the injunction will cause irreparable harm to Lupin, should the Federal Circuit reverse the entry of the Order. *See, e.g., Standard Havens Prods.*, 897 F.2d at 512. This is the reverse of the analysis on Shionogi's motion for a preliminary injunction, where the focus was on the claimed harm to Shionogi. The preliminary injunction is causing and will continue to cause irreparable harm to Lupin.[4] The same kinds of harms that this Court found supported the grant of the preliminary injunction similarly mandate a stay or modification of that injunction pending appeal. On the preliminary injunction motion, this Court found that the loss of the 180-day exclusivity to Lupin was outweighed by the hardships to Shionogi, but the Court did not discuss and apparently did not consider the other harms to Lupin. These other harms – irrecoverable loss of market share, potential destruction of the Fortamet® market by Shionogi's neglect, a cap on damages that is below the likely actual damages, and loss of the one-year advantage over the next generic - are central to the instant motion for a stay.

The most significant harm to Lupin is from the fact that Watson may – and most likely will – launch its generic product, while Lupin is barred from entering the market. As a result, Lupin will suffer irreparable injury from Watson's ability to capture the generic market, (*see*

[4] Notably, Lupin's stock price dropped in reaction to the news of the preliminary injuction order. http://in.reuters.com/finance/stocks/overview?symbol=LUPN.NS (attached as Attachment B). There is no support in the record or elsewhere for plaintiff's assertion at oral argument that the generic company's business model is to sell for a month or two and then withdraw from the market. To the contrary, Lupin (like other generic pharmaceutical companies) relies on establishing a market which it supplies over time, as described in the Hoffman declaration. The fact that Lupin sells so many prescriptions in the United States attests to this. (*See also* Lupin's 2011 Annual Report, Declaration of Mark Gleason and Ivan Hofmann at Exh. 8.)

Hoffman Decl. at ¶¶ 8-11), while Shionogi will suffer the same irreparable injuries it feared as a result of Lupin's generic competition.

First, Lupin will lose potential market share that it will never be able to recover. The only evidence before the Court concerning the effect on Lupin of other generic competitors is the declaration of Robert Hoffman, Lupin's Senior Vice President of Sales & Marketing. Mr. Hoffman explained that if Watson is permitted to sell its product while Lupin is precluded, Lupin will lose market share and customers that it will not be able to regain. Lupin anticipated net profits of over $29 million for the first year after it launched, assuming that Watson also was in the market and that the two companies would split the generic market between them. If Watson is in the market alone, Lupin predicted that by the time it is able to enter the market, it will have only a 10-15% market share in comparison to the 33-50% share it otherwise would have had (depending on whether Mylan, Inc. also is selling). (Hoffman Decl. at ¶¶ 11, 18-19.) This Court set the bond at only $15 million,[5] looking at only part of Lupin's loss of sales in the first year, discounting its loss of sales during the first 180 days, and not taking into account its permanent loss of market share.[6] (Slip Op. at 21-22.) Thus, even if this loss of market share could be quantified, Lupin will not be able to recover sufficient money damages because the size of the

[5] Despite stating that a bond hearing would be held, the Court set the amount of the bond, based on a number given for the first time by plaintiff's counsel during oral argument. Plaintiff had not contested in its reply papers Lupin's request for a bond in the amount of $54 million, and gave no support for its proposal that $10-$15 million would be sufficient to cover Lupin's damages.

[6] The Court stated that Lupin "often pointed out" that "its greatest profits would be accrued during the 180-day exclusivity period." (Slip Op. at 22.) This is not, however, what Lupin argued in its brief or at oral argument. Lupin not only noted that the 180 days would run, even if it was not on the market and that this was irreparable, but also it identified the full year before the next competitor could launch as its time of greatest lost market opportunity and that being off the market while another generic competitor was able to sell would result in permanent loss of market share. (Hoffman Decl. ¶¶ 16-20.) Watson is able to launch at any time, including during the 180 days, since it is an "authorized" generic. Watson was kept off the market by the standstill order, now lifted by the entry of the injunction order, not by the Hatch-Waxman Act.

bond is less than its likely damages and the bond likely caps the damages. *Pharmacia and Upjohn Co. v. Ranbaxy Pharmaceuticals, Inc.*, 85 Fed. Appx. 205, 215 (Fed. Cir. 2003). In addition, this Court found that loss of market share was an irreparable harm to Shionogi, especially in view of the declining Fortamet® market;[7] similarly, it is an irreparable harm to Lupin.

Second, Lupin will be harmed by the declining market. Unlike many situations in the reported cases, barring Lupin from the market now will not merely "time-shift" its profits to the time when it is able to enter. *See Albany Molecular Research, Inc. v. Dr. Reddy's Labs, Ltd.*, 2010 WL 2516465, at *11 (D.N.J. June 14, 2010); *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, Civ. No. 09-MD-2118, 2011 U.S. Dist. LEXIS 54062, at *10. Shionogi still apparently has no intention of devoting resources to maintaining the market for Fortamet®, despite its decline and despite the strong generic competition from other metformin products. (*See* Lupin Injury Slides #3 and 10 and cited exhibits.) By the time Lupin is able to re-enter the market, Shionogi may have destroyed it beyond recovery.[8] (*See* Opinion at 18 ("this Court finds that a loss of market position accompanied by market diminution presents an even stronger case for irreparability.").)

Third, Lupin will lose its 180-day exclusivity period, which began to run when it first launched its product and will continue to run even while it is enjoined. This Court discounted

[7] The Court took the declining market into consideration as harm to Shionogi, despite the fact that Shionogi is largely responsible for its market decline and therefore the harm that flows from it is foreseeable and self-inflicted. (*See* Slip. Op. at 19.) Several years ago, Shionogi anticipated generic competition and identified the need for promotional activities to maintain its market share even without generic competition. Nevertheless, Shionogi ceased all promotional activities in August 2010 and withdrew from the 500 mg market for months. It is not surprising that the result was a decline in market share, completely unrelated to generic competition. (*See* Lupin Injury Slides #10 and Binder Tabs 2, 6 and 9.)

[8] Had Lupin been permitted to stay on the market, its sales and promotion efforts likely would have maintained and perhaps expanded the market.

this harm because it was foreseeable. (Slip. Op. at 18-19.) While some courts have taken the same position, others have disagreed and found that the loss of exclusivity is a harm to the generic company that should be considered. It is, after all, part of a statutory scheme to encourage generic companies to develop generic alternatives and bring them to market as promptly as possible. *See In re Cyclobenzaprine Hydrochloride Extended Release Capsule Litigation,* 2011 U.S. Dist. LEXIS 54062, at *9-10 (D. Del. May 12, 2011) (calling running of 180-day exclusivity a "legitimate concern"); *Novartis Corp. v. Teva Pharms. USA, Inc.,* 2007 U.S. Dist LEXIS 42163, at *96-100 (D.N.J. June 11, 2007) (taking the loss of 180-day exclusivity into account, and noting that the brand company could have moved for an injunction before the generic launched, since the date of the expiration of the 30-month stay had been known for years).

Similarly, Lupin will lose its one-year advantage for having developed its product and filed its ANDA one year before any other generic competitor. Unlike the 180-day exclusivity, the loss of this advantage was not a foreseeable harm from Lupin's launch, but a consequence of the pace of the litigation. The chance that this litigation will be completed by June 2012, when Mylan's 30-month stay expires, is remote. In fact, this Court estimated that the case will not be completed in the district court until December 2012. (Slip Op. at 21.) Under the terms of the current injunction order, that will be one year after Watson is likely to have launched its generic product and six months after Mylan may be on the market – while Lupin is precluded despite being the first generic to file its ANDA.

VI. HARM TO OTHERS IS NOT AS GREAT AS HARM TO LUPIN

All of the harms that this Court found to support the issuance of a preliminary injunction will befall Shionogi even though Lupin is enjoined, as soon as Watson enters the market. Thus,

rather than maintaining the *status quo*, the preliminary injunction shifts the playing field radically against Lupin without protecting Shionogi.[9]

The Court found that Shionogi's possible loss of market share to a generic competitor was an irreparable injury when combined with the price erosion Shionogi claimed would follow. This combination of harms also will follow from Watson's entry into the market. While the existence of an authorized generic does not, by itself, mean that the brand cannot show irreparable harm from the entry of another generic competitor, Shionogi here has failed to make any showing that an injunction against Lupin will rectify any of the irreparable harms found by the Court once Watson launches. Shionogi introduced no information or evidence showing that claimed harm from Lupin's launch would be different from its harm from Watson's launch.

In reaching its conclusion, this Court relied on three cases. One is *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH,* 237 F.3d 1359, 1368 (Fed. Cir. 2001), (Slip Op. at 17), but *Purdue Pharma* held that Purdue "was entitled to a rebuttable presumption of irreparable harm" and that therefore "the burden properly was on" the generic. Subsequent to *Purdue Pharma,* the Supreme Court held that such a presumption was improper and the burden remains on the party seeking the injunction to prove irreparable harm. *Ebay, Inc. v. Merc Exchange, L.L.C.*, 547 U.S. 388 (2006). In contrast to cases where the plaintiff introduced evidence and demonstrated that it would lose market share, price erosion existed and the resulting harm would be irreparable, Shionogi made no specific showing and introduced no evidence. The 50% loss of market share cited by the Court was an estimate asserted by counsel at oral argument, in response to a question from the Court – no data was submitted in support of the size of the loss nor that its cause was

[9] The best protection for Shionogi would be if this Court could extend the standstill order, keeping Watson as well as Lupin off the market.

entirely the result of Lupin's launch rather than, for example, the declining market and failure to promote.

The Court's acceptance of Shionogi's unsupported assertion that "price erosion" has occurred is even more puzzling, since Shionogi has steadily raised its prices over the years and its reaction to Lupin's launch was to raise its prices even more dramatically. (Lupin Injury Binder at Tab 20.) The Court suggested at oral argument that this might be a temporary price increase, followed by falling prices, but notably Shionogi has never made this assertion and its counsel did not express agreement with the Court's suggested scenario at oral argument. To the contrary, Shionogi represented to the Court through declarations by its experts and its company representative, as well as at argument, that it was going to be compelled to lower its prices. It did not inform the Court that, to the contrary, it had raised its prices, an action that it took not even two weeks after submitting its reply brief arguing that its prices would have to be lowered.[10] The facts therefore completely contradict Shionogi's claim of price erosion.

The Court also relied on *Abbott Labs. v. Sandoz, Inc.,* 544 F.3d 1341, 1361-62 (Fed. Cir. 2008), for the proposition that market share and revenue loss due to generic entry is irreparable injury to the brand, even if there are licensed generic producers on the market. In *Abbott Labs,* however, the appellate decision upheld the District Court's finding that the plaintiff had shown an "*added* erosion of markets, customers and prices" from the entry of the unauthorized generic. *Id.* at 1362 (emphasis added). In contrast, Shionogi made no attempt to distinguish the harm it claimed from Lupin's entry to the market and the entry to the market of Watson or any other generic. Not only did Shionogi never provide support that there would be additional irreparable harm from Lupin's entry to a market where Watson already was selling a generic, Shionogi

[10] Shionogi did not produce this information to Lupin in discovery either; Lupin learned the fact through market research.

argued to the contrary. As this Court noted, according to Shionogi, part of the harm supposedly caused by Lupin's launch was the ability of Watson to sell its generic product, and the royalties it may receive from Watson[11] will not mitigate its irreparable injuries. (Slip. Op. at 16.)

The third case on which the Court relied was *Bosch v. Pylon Mfg. Corp.*, No. 2011-1096, slip op. (Fed. Cir. Oct. 12, 2011) which is inapt when considered in its entirety. In *Bosch*, the Federal Circuit did not find that loss of market share and price erosion necessarily were irreparable harm. As the Federal Circuit has held, the plaintiff is required to make a specific showing that these factors will cause it irreparable injury in the particular case before an injunction should issue. *E.g., Altana Pharma AG, 566 F.3d 999.* The *Bosch* decision details the specific and extensive evidence introduced by the plaintiff showing its actual loss of market share and customers from the particular defendant in the case. Bosch detailed the specific customers lost (such as Wal-Mart) and identified other customers for whom the two competed, despite the presence of other potentially infringing competitors on the market whom Bosch had not yet sued. The *Bosch* court also noted that the defendant did not introduce any evidence to rebut the plaintiff's evidence of price erosion. In contrast, here not only did Shionogi show no evidence of price erosion, but also Lupin introduced unrebutted evidence that Shionogi has raised not lowered its prices. Finally, the *Bosch* court found these economic injuries to be irreparable in large part because the plaintiff proved that the defendant would be unable to pay a judgment – not because they could not be quantified. *See, e.g, Bosch.,* slip.op. at 19 ("It also contends that Pylon's inability to satisfy a judgment renders its injury irreparable.") and 23 ("More importantly, the questionable financial condition of both Pylon and its parent company reinforces the inadequacy of a remedy at law").

[11] Shionogi did not mention its savings from the royalties it no longer has to pay Watson.

Shionogi's claimed loss of goodwill does not outweigh the harm to Lupin if the injunction is not stayed. The Court found Shionogi's claimed loss of goodwill merely speculative, but nevertheless held that this speculation "must factor into the Court's analysis." (Slip. Op. at 14.) Shionogi was concerned it might lose goodwill because Lupin's manufacturing issue (solved in one day by moving the coating pan) might somehow lead to customer dissatisfaction with an inferior Fortamet® product. This speculation is disproven by the fact that Lupin's product has been on the market for two months and Shinogi points to no issues or complaints from customers, wholesalers or regulators about its quality.[12] Watson similarly experienced a manufacturing issue, but one of much greater import and difficulty, since it kept their 500 mg product off the market for over one year. (Plaintiffs have not disclosed the nature of this manufacturing problem.) Thus, Shionogi's speculative and unsupported concern that manufacturing issues can result in inferior products that will harm goodwill exists at least as much with the Watson product.

The Court also found that possible customer blame of Shionogi for price fluctuations following a generic launch was no more than "speculative," but nevertheless since it was a "potential" loss of goodwill it too should be factored into the analysis. (Slip. Op. at 14.) Shionogi claimed that the "price fluctuations" would result from the availability of a lower-priced generic product followed by its absence because of Shionogi's litigation activities. Since that is exactly what has happened by Lupin's launch and the entry of the preliminary injunction, this "speculative" harm – if it exists – is caused as much by the injunction as by Lupin's launch. Similarly, if the price fluctuation harm is caused by the brand's raising prices in response to the

[12] The Court recognized that although Lupin's product had been sold to distributors for only two weeks before the standstill order was entered, Lupin's product continued to be distributed to retailers and customers. (Slip. Op. at 20.)

generic launch, again this will happen when Watson launches its generic product and it has happened over the years and Shionogi has raised its price 11 times over the past four years, including since Lupin's launch. (Lupin Injury Binder at Tab 20.)

VII. PUBLIC INTEREST IS NOT NEUTRAL

The Court found that the public interest in protecting patent rights are balanced by the public interest in increasing the availability of generic drugs. (Slip. Op. at 20.) As stated at the hearing, the irregularities in the PTO renders this balance one-sided and thus favors continued public access to generic drugs.

VIII. CONCLUSION

The preliminary injunction Order entered December 6, 2011, should be stayed pending review by the Federal Circuit. In the alternative, the preliminary injunction Order should be modified to provide that it will be stayed immediately and without further action needed by any party if another generic Fortamet product enters the market.

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